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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/848,806	05/04/2001	Jen Sheen	00786/389002	7904

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EXAMINER	
COLLINS, CYNTHIA E	
ART UNIT	**PAPER NUMBER**
1638	

DATE MAILED: 12/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/848,806	SHEEN, JEN	
	Examiner	Art Unit	
	Cynthia Collins	1638	

-- The MAILING DATE of this communicati n appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 October 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-57* is/are pending in the application.

4a) Of the above claim(s) *9 and 17-53* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,10-16 and 54-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10/14/03 and 12/26/02
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The Amendment filed October 14, 2003 has been entered.

Claims 1, 5, 6, 8 and 10 are currently amended.

Claims 9 and 17-53 are withdrawn from consideration.

Claims 54-57 are newly added.

Claims 1-57 are pending.

Claims 1-8, 10-16 and 54-57 are examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

Information Disclosure Statement

Initialed and dated copies of Applicant's IDS forms 1449, filed December 26, 2002 and October 14, 2003, are attached to the instant Office action.

Claim Rejections - 35 USC § 112

Claims 1-7 and 10-16 remain rejected, and claims 54 and 56 are rejected, under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the office action mailed April 10, 2003.

Applicant's arguments filed October 14, 2003, have been fully considered but they are not persuasive.

Without reference to which rejection under 35 U.S.C. 112, first paragraph, is being addressed (written description versus enablement), Applicant points out that the scope of claim 1 is now limited to sequences that are highly identical and structurally similar to SEQ ID NO:1, as claim 1 as amended now requires a nucleic acid molecule encoding a polypeptide of SEQ ID NO:1 or having at least 80% identity to SEQ ID NO:1. Applicant also argues that the specification adequately describes such molecules. Applicant additionally argues that undue trial and error experimentation would not be required to identify the nucleic acids encompassed by the amended claims. Applicant additionally argues that one skilled in the art could easily test whether overexpression of theses nucleic acids in plants confers disease resistance, as one need only apply the techniques disclosed in the specification to identify plants that overexpress a CDPK nucleic acid and exhibit disease resistance. (reply pages 12-13).

The rejection is maintained because nucleic acid molecules encoding a polypeptide of SEQ ID NO:1 or having at least 80% identity to SEQ ID NO:1 whose overexpression in a plant increases the level of resistance to a disease-causing pathogen are not described. While claim 1 is now limited to sequences having a specific structure or having a specific amount of similarity thereto, the specification does not describe a representative number of species falling within the scope of the claimed genus. The specification indicates only that a plant having increased disease resistance may be produced by overexpressing a calcium-dependent protein kinase polypeptide such as CDPK2 (SEQ ID NO:2) or CDPK4 (SEQ ID NO:4) or polypeptides that consist essentially of the protein kinase domain of a CDPK or CDPKs that are orthologs of *Arabidopsis*

CDPKs (page 2 lines 1-21; page 11 lines 17-21), but such plants are not described. Accordingly, the specification does not describe the specific structural features of nucleic acid molecules encoding a polypeptide having at least 80% identity to SEQ ID NO:1 that are correlated with the function of increasing the level of resistance to a disease-causing pathogen upon overexpression in a plant, or that are correlated with calcium dependent protein kinase activity. Furthermore, that undue experimentation would not be required to identify the nucleic acids encompassed by the amended claims is not germane to the rejection for inadequate written description, as nucleic acids that have not been identified have also not been described.

Claims 1-8 and 10-16 remain rejected, and claims 54-57 are rejected, under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons of record set forth in the office action mailed April 10, 2003.

Applicant's arguments filed October 14, 2003, have been fully considered but they are not persuasive.

Without reference to which rejection under 35 U.S.C. 112, first paragraph, is being addressed (written description versus enablement), Applicant points out that the scope of claim 1 is now limited to sequences that are highly identical and structurally similar to SEQ ID NO:1, as claim 1 as amended now requires a nucleic acid molecule encoding a polypeptide of SEQ ID NO:1 or having at least 80% identity to SEQ ID NO:1. Applicant also argues that the specification adequately describes such molecules. Applicant additionally argues that undue trial

and error experimentation would not be required to identify the nucleic acids encompassed by the amended claims. Applicant additionally argues that one skilled in the art could easily test whether overexpression of theses nucleic acids in plants confers disease resistance, as one need only apply the techniques disclosed in the specification to identify plants that overexpress a CDPK nucleic acid and exhibit disease resistance. (reply pages 12-13).

The rejection is maintained because the claimed invention is not enabled. While claim 1 is now limited to sequences having a specific structure or having a specific amount of similarity thereto, the specification does not provide sufficient guidance for one skilled in the art to determine, without undue experimentation, how to overexpress a nucleic acid encoding a polypeptide of SEQ ID NO:1 in a plant in a manner that would increase the level of resistance to a disease-causing pathogen. While the specification discloses techniques that could be used to identify plants that overexpress a nucleic acid encoding a polypeptide of SEQ ID NO:1 and that exhibit disease resistance, the specification does not provide sufficient guidance with respect to how to overexpress a nucleic acid encoding a polypeptide of SEQ ID NO:1 in a plant in such a manner that the plant would exhibit resistance to any particular disease. For example, the specification does not disclose where or how or how much in the plant to express the nucleic acid to produce resistance to a specific disease. Furthermore, the specification also does not provide sufficient guidance for one skilled in the art to determine, without undue experimentation, which nucleic acid molecules encoding a polypeptide having at least 80% identity to SEQ ID NO:1 would increase the level of resistance to a disease-causing pathogen when overexpressed in a plant, and which would not. Absent such guidance, one skilled in the art would have to resort to trial and error testing of every sequence having at least 80% identity to

SEQ ID NO:1 to discriminate between operative and inoperative embodiments. Without guidance, such testing could entail expressing the numerous sequences that fall within the scope of the claims under the control of a variety of different promoters in a variety of different plants and screening those plants for their resistance to a variety of different disease-causing pathogens, or alternatively, screening a variety of different plants for natural variants that overexpress the numerous sequences that fall within the scope of the claims and screening those plants for their resistance to a variety of different disease-causing pathogens. The undue experimentation lies in selecting which sequences to express and under what conditions to obtain resistance to a particular disease-causing pathogen, rather than in employing techniques that could be used to identify plants that overexpress a nucleic acid or that exhibit disease resistance.

Claim 10 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "consists essentially of", for the reasons of record set forth in the office action mailed April 10, 2003.

Applicant's arguments filed October 14, 2003, have been fully considered but they are not persuasive.

Applicant argues that the rejection should be withdrawn in light of the amendment of the claim to reflect that a CDPK polypeptide consists of the CDPK protein kinase domain itself, absent other portions of the full-length molecule (reply 15).

The rejection is maintained because the transitional phrase "consists essentially of" now referees the CDPK protein kinase domain itself, and it is unclear what would not materially affect the CDPK protein kinase domain itself.

Claim Rejections - 35 USC § 102

Claims 1-8 and 10-16 remain rejected, and claims 54-57 are rejected under 35 U.S.C. 102(b) as being anticipated by Sheen (WO 98/26045, published 18 June 1998), for the reasons of record set forth in the office action mailed April 10, 2003.

Applicant's arguments filed October 14, 2003, have been fully considered but they are not persuasive.

Applicant argues that it is not inherent in the cited reference that the engineered plant cells were resistant to disease, and that the reference is silent with respect to whether CDPK regulates disease resistance genes. Applicant also argues that the Office may not rely on the specification to support an argument of inherency, and must provide some evidence in the prior art in support of the assertion that expression of a nucleic acid encoding a calcium dependent protein kinase as set forth in claim 1 would increase the level of resistance of a plant to a disease-causing pathogen (reply pages 16-17).

The rejection is maintained because Sheen teaches the same method as set forth in the rejected claims, namely a) providing a plant cell overexpressing a nucleic acid encoding a CDPK of SEQ ID NO:1 or having at least 80% identity to SEQ ID NO:1, and b) regenerating a plant, wherein the CDPK polypeptide is expressed in said plant. The specification is not relied upon to support the argument of inherency, and no additional evidence in the prior art in support of the assertion that expression of a nucleic acid encoding a calcium dependent protein kinase as set forth in claim 1 would increase the level of resistance of a plant to a disease-causing pathogen is needed. Because the rejected claims set forth no positive method steps that would distinguish the claimed method from the method disclosed in the prior art, the method taught by Sheen, being

the same as the method set forth in the rejected claims, must necessarily increase the level of resistance of a plant to a disease-causing pathogen.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-8, 10-16 and 54-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lusso et al. (WO 99/02655, published 21 January 1999) in view of Urao et al. (SPTREMBL Accession No. Q39016, 01 November 1996, Calcium-dependent protein kinase ATCDPK2 from *Arabidopsis thaliana*).

The claims are drawn to a method of producing a plant having increased resistance to any disease-causing plant pathogen, by regenerating any plant from a plant cell, including a monocotyledonous or dicotyledonous plant cell and including transgenic plant cells, that overexpress a nucleic acid molecule encoding a calcium-dependent protein kinase polypeptide (CDPK) of SEQ ID NO:1 or having at least 80% identity to SEQ ID NO:1, wherein the nucleic acid molecule comprise an inducible promoter.

The teachings of Lusso et al. were set forth in the previous action (mailed April 10, 2003) at pages 7-8. Lusso et al additionally teach that their method can be practiced using a polynucleotide that hybridizes to the disclosed polynucleotide encoding a soybean CDPK under

moderately stringent conditions, or using a polynucleotide having at least 70% sequence identity with the disclosed polynucleotide encoding a soybean CDPK (pages 9-11).

Lusso' et al. do not teach a nucleic acid molecule encoding a calcium-dependent protein kinase polypeptide (CDPK) of SEQ ID NO:1 or having at least 80% identity to SEQ ID NO:1.

Urao et al. (SPTREMBL Accession No. Q39016, 01 November 1996, Calcium-dependent protein kinase ATCDPK2 from *Arabidopsis thaliana*) teach a nucleic acid molecule encoding a calcium-dependent protein kinase polypeptide (CDPK) of SEQ ID NO:1, which has 77 percent sequence similarity with the polynucleotide encoding a soybean CDPK taught by Lusso et al. (see attached sequence alignment).

Given the success of Lusso et al. in producing a plant having increased resistance to a disease-causing plant pathogen by regenerating a plant from a plant cell that overexpresses a polynucleotide encoding a soybean calcium-dependent protein kinase polypeptide, and given the further teaching that their method can be practiced using a polynucleotide that hybridizes to or has at least 70% sequence identity with their disclosed polynucleotide, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to practice the method disclosed by Lusso et al. with any polynucleotide that encodes a calcium-dependent protein kinase and that hybridizes to or has at least 70% sequence identity with their disclosed polynucleotide, such as the polynucleotide encoding the calcium-dependent protein kinase ATCDPK2 from *Arabidopsis thaliana* taught by Urao et al., without any surprising or unexplained results. Accordingly, one skilled in the art would have been motivated to generate the claimed invention with a reasonable expectation of success. Thus, the claimed invention

would have been *prima facie* obvious as a whole to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Remarks

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC
December 16, 2003

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~180~~ 1638